

201-14255

**Richard Hefter**

01/09/2003 12:58 PM

To: NCIC HPV@EPA

cc:

Subject: RE: EPA comments on Lactic acid HPV Challenge submission

Response to EPA comments submitted on the Lactic Acid HPV Challenge submission.

----- Forwarded by Richard Hefter/DC/USEPA/US on 01/09/03 12:55 PM -----



**"Dongen, Ton van"**  
<t.van.dongen@purac.  
com>

01/09/03 04:38 AM

To: Richard Hefter/DC/USEPA/US@EPA

cc:

Subject: RE: EPA comments on Lactic acid HPV Challenge submission

Dear Mr. Hefter,

Please find enclosed with this mail the following two documents:

79-33-4 HPV robust summary 2n version

79-33-4 HPV data 2n version

The comments given by the EPA in the September 19 letter of Mr. Hernandez, have led to an update on the following:

- Physicochemical properties.

A discussion on the melting point for the anhydrous form of the racemic mixture has been added to the robust summaries. However, from this discussion it will be clear that the melting point of crystallized lactic acid is not a straight forward issue. We have given the information available in public literature.

- Environmental fate.

A photodegradation calculation has been made using EPIWIN v 3.10. The results have been included in both the robust summary as well as in the test plan.

A Fugacity calculation has been made using EPIWIN v3.10. The results have been included in both the robust summary as well as in the test plan.

- Health effects.

Additional information on the study results submitted have been included in both the robust summary as well as in the test plan. Results from public literature often do not contain the detailed information as requested under the HPV program. However, due to the fact that L(+) lactic acid is part of the human metabolism, we do not see any problems as far as health effects are concerned and we would like to argue that thus this detailed information does not add to the safety evaluation of this product. We can make available the public literature upon request.

We trust that we have informed you sufficiently. However, please feel free to contact me in case you would need additional information

In the meantime I remain, yours sincerely,

2003 JAN 17 PM 12:30  
RECEIVED  
OPT NOIC

Ton van Dongen  
PURAC Division QA&RA Manager

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79-33-4 HPV data 2n version.pdf



79-33-4 HPV robust summary 2n version.pdf